



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/539,765

02/08/2006

Michael Grant

1662.004US2

2018

45836

7590

03/17/2008

SCHWEGMAN, LUNDBERG & WOESSNER/NIH

PO BOX 2938

MINNEAPOLIS, MN 55402-0938

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,765	Applicant(s) GRANT, MICHAEL	
	Examiner KAILASH C. SRIVASTAVA	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/20 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Preliminary Amendment filed 20 June 2005 regarding application priority data is acknowledged and entered.
2. Please note that the correct Serial Number of your Application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/539,765, not unassigned. Please ensure that the correct U.S. Serial Number for this Non-Provisional U.S. application is cited in all future correspondence with this Office.
3. The assigned Art Unit location of your application in the USPTO is 1657. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1657.
4. The assigned Examiner to your above-cited application in the USPTO is Dr. Kailash C. Srivastava. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Claims Status

5. Claims 1-61 are pending.

Election /Restriction

6. This application contains the following groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372.

Group I, consisting of claims 1-42 drawn to a method to segregate pathogenic and non-pathogenic microbes and to enrich and detect a target pathogenic enterohemorrhagic, enteropathogenic or enterotoxigenic microorganism; and

Group II, consisting of Claims 43-50 drawn to a kit to enrich and detect a microbe.

Group III, consisting of claims 51-55, drawn to another kit to detect bacteria.

Group IV, consisting of claims 56-61, drawn to a third A kit comprising packaging material, culture media, a first pH modifier, and a second pH modifier, wherein addition of the first pH modifier to the culture media produces an acidic medium and addition of the second pH modifier to the acidic medium produces a growth medium.

Inventions are Independent and Distinct

7. The inventions listed in Groups I-IV above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The patent rules under 37 C.F.R. §1.475 for Unity of Invention (Paragraphs (a), (b) and (c)) are cited below:

§1.475 Unity of Invention before the International Searching Authority, the International Preliminary Examining Authority and during the National Stage

(a) An International and National Stage Application shall relate to one invention only, or to a group of inventions so linked as to form a general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as whole, makes over the prior art.

(b) An International or a National stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

The groups of invention outlined above fall within category (2), a product and a menthol of use of said product.

8. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.2 does not provide for multiple compositions, or multiple methods of making a composition, or multiple methods of use of a composition within a single application. Thus, the first appearing composition is combined with a corresponding first method of making said composition (if applicable) and/ or use of said composition. However, the additional composition and method claims each constitute a separate inventive Group.

In addition to the requirement that a Group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, e.g., as a composition and a method of use of said composition, must have a special technical feature that unites them. See Patent rules under 37 C.F.R. §1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

The special technical feature of the group I method (i.e., Claims 1-42) and product (i.e., Claims 43-50 encompassing a kit) is that of differentiating different categories of a pathogenic microorganism and media therefor, which are notoriously well known in the art (See for e.g., Padhye, et al. 1992. *Escherichia coli* O157:H7: Epidemiology, Pathogenesis, and Methods for Detection in Food. *Journal of Food Protection*, Volume 55, No. 7, Pages 555-565). Since no special technical feature exists between the Method of Group I and products of groups II-IV, there is no unity of invention.

The special technical features of the remaining Groups are distinct as described above.

9. In accordance with 37 C.F.R. §1.499, applicant is required, in response to this Office Action, to elect a single invention Group among those listed supra to which the claims must be restricted.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 C.F.R §1.143).

Species Election

11. This application contains claims directed to different methods/compositions comprised of a variety of ingredients. Therefore, if the applicant elects anyone of Groups I-IV above, the applicant must also make election of species by electing a single species from each of the following categories as applicable to the elected Groups I-IV:

- i. Only one among pathogenic or non-pathogenic *Escherichia coli* as listed in Claim 1;
- ii. Only one pathogenic *Escherichia coli* among: enterohemorrhagic *Escherichia coli*, enteropathogenic *Escherichia coli*, or enterotoxigenic *Escherichia coli* as listed in claims 2, 7 and 48;
- iii. Only one target microbes among those listed in Claim 1, 5 or 50;
- iv. Only one medium pH range among those listed in Claims 9-11;
- v. Only one selective agent among: antibody, antibiotic, bacteriophage, inorganic supplement, nutritional supplement, organic supplement, selenite, sorbitol, or tellurite as listed in Claims 17-23, 32-39 and 42;
- vi. Only one temperature range among those listed in Claims 27-30;
- vii. Only one of the organic acids as listed in Claims 57-58; and
- viii. Only one of the inorganic acids as listed in Claims 59-60.

In accordance with 37 C.F.R. §1.499, applicant is required that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species [See, M.P.E.P. §809.02(a)].

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims

that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. §821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. §1.116; amendments submitted after allowance are governed by 37 C.F.R. §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. §804.01.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber, can be reached on (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

/Dr. Kailash C Srivastava/
Examiner, Art Unit 1657

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1657
(571) 272-0923

27 March 17, 2008

/David M. Naff/
Primary Examiner, Art Unit 1657